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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/565,415

02/20/2007

Anthony Simmons

UTSG:263US

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EXAMINER

GANGLE, BRIAN J

ART UNIT

PAPER NUMBER

1645

MAIL DATE

DELIVERY MODE

07/23/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/565,415	Applicant(s) SIMMONS ET AL.	
	Examiner Brian J. Gangle	Art Unit 1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 May 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,4,6,7,12-20,28-30,36,39-41 and 46 is/are pending in the application.
- 4a) Of the above claim(s) 28-30,36,39-41 and 46 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 3-4, 6-7, and 12-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Applicant's amendment and remarks, filed on 5/1/2009, are acknowledged. Claims 1 and 14 are amended. Claims 2, 5, 22, 37-38, and 47 are cancelled. Claims 1, 3-4, 6-7, 12-20, 28-30, 36, 39-41, and 46 are pending. Claims 28-30, 36, 39-41, and 46 are withdrawn. Claims 1, 3-4, 6-7, and 12-20 are currently under examination.

Claim Objections Maintained

The objection to claims 1, 6, and 15, because the claims contain the acronyms HSV and HIV, is maintained for the reasons set forth in the previous office action. Applicant has not addressed this objection.

While acronyms are permissible shorthand in the claims, the first recitation should include the full recitation followed by the acronym in parentheses. Appropriate correction is required.

Claim Rejections Withdrawn

The rejection of claims 7 and 22 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, is withdrawn in light of applicant's amendment thereto.

The rejection of claims 1-2 and 12 under 35 U.S.C. 102(b) as being anticipated by Burton *et al.* (US Patent 6,376,170, April, 2002; IDS filed 12/19/2006), is withdrawn in light of applicant's amendment thereto.

The rejection of claims 1-2, 12-16, 19-20, and 22 under 35 U.S.C. 102(b) as being anticipated by Burton *et al.* (US Patent 6,156,313, 2000; IDS filed 12/19/2006), is withdrawn in light of applicant's amendment thereto.

The rejection of claims 1-2, 12-16, 19, and 22 under 35 U.S.C. 102(b) as being anticipated by Tso *et al.* (US Patent 5,932,448, 1999; IDS filed 12/19/2006), is withdrawn in light of applicant's amendment thereto.

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The rejection of claims 1-4, 12-16, 19-20, and 22 under 35 U.S.C. 103(a) as being unpatentable over Burton *et al.* (US Patent 6,156,313, 2000; IDS filed 12/19/2006) in view of Alvarez-Vallina *et al.* (Eur. J. Immunol., 26:2304-2309, 1996), is withdrawn in light of applicant's amendment thereto.

The rejection of claims 1-2, 5, 12-16, 19-20, and 22 under 35 U.S.C. 103(a) as being unpatentable over Burton *et al.* (US Patent 6,156,313, 2000; IDS filed 12/19/2006) in view of Nicola *et al.* (J. Virol., 72:3595-3601, 1998; IDS filed 12/19/2006), is withdrawn in light of applicant's amendment thereto.

The rejection of claims 1-2, 12-20, and 22 under 35 U.S.C. 103(a) as being unpatentable over Burton *et al.* (US Patent 6,156,313, 2000; IDS filed 12/19/2006) in view of Hostetler (US Patent 5,580,571, 1996), is withdrawn in light of applicant's amendment thereto.

The rejection of claims 1-2, 6-7, 12-16, 19, and 22 under 35 U.S.C. 103(a) as being unpatentable over Tso *et al.* (US Patent 5,932,448, 1999; IDS filed 12/19/2006), is withdrawn in light of applicant's amendment thereto.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 3-4, 6-7, and 12-20 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

It is apparent that the monoclonal antibodies DL11 or 1D3 (or the sequences of the hypervariable regions of said antibodies) are required to practice the claimed invention. As such

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they must be readily available or obtainable by a repeatable method set forth in the specification, or otherwise readily available to the public. If it is not so obtainable or available, the requirements of 35 USC 112, first paragraph, may be satisfied by a deposit of the hybridomas producing said antibodies.

The process disclosed in the specification does not appear to be repeatable and it is not clear that the claimed method will work with commonly available material per se. If a deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by Applicants, or a statement by an attorney of record over his or her signature and registration number, stating that the instant invention will be irrevocably and without restriction released to the public upon the issuance of a patent, would satisfy the deposit requirement made herein. If a deposit has not been made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 CFR 1.801-1.809 and MPEP 2402-2411.05, Applicant may provide assurance of compliance by affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number showing that:

(a) during the pendency of the application, access to the invention will be afforded to the Commissioner upon request;

(b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;

(c) the deposit will be maintained in a public depository for a period of 30 years, or 5 years after the last request or for the enforceable life of the patent, whichever is longer;

(d) a test of the viability of the biological material at the time of deposit (see 37 CFR 1.807); and

(e) the deposit will be replaced if it should ever become inviable.

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian J. Gangle whose telephone number is (571)272-1181. The examiner can normally be reached on M-F 7-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Mondesi can be reached on 571-272-0956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Brian J Gangle/
Examiner, Art Unit 1645

/Robert B Mondesi/
Supervisory Patent Examiner, Art Unit 1645